REMARKS

Rejection under UCS 35, 112, first paragraph

The Examiner has rejected Claim 85 as containing subject matter that is not described in the specification in such a way as to enable one skilled in the art to which it pertains. In particular, the Examiner states:

> The instant claim recites "physiological levels of human serum albumin" and the applicant's Remarks [in the previous response] refer to pages 26-27 of the specification as supporting this claim. In reading these pages the examiner has found no reference to "physiological levels of human serum albumin". The instant portion of the specification teaches that 60 mg/ml of human serum albumin was used top test the binding of 5A11 antibody to $^{125}IA\beta_{1-40}$. If the applicant can show somewhere in the specification or in some prior art reference where 60 mg/ml is taught to be "physiological levels of human serum albumin" then they may use this term. Other wise they should claim what is taught in the specification.

Attached as Exhibit A is a description of a research project on the website of the Australian Proteome Analysis Facility (APAF Ltd), Australia's premier proteomics institution. According to their website, APAF Ltd was the birthplace of the term proteomics in 1995 and the first high throughput lab worldwide. APAF research and development has continued in all areas of technology development and industry, providing world leading advances and services for over a decade. The research project described relates to a novel cyclic immunodepletion technique for the removal of highly abundant proteins in human plasma, thereby enabling the study of low abundant protein markers present in plasma. The second paragraph of the description of the research project indicates that albumin is present at levels of approximately 60 mg/ml. It is respectfully submitted that the above-stated rejection has been addressed and withdrawal of the rejection is requested.

Characterization of Suzuki reference

In the pending Office Action the Examiner cited U.S. Patent No. 5,955,317 to Suzuki, *et al.*, as "of interest" to the pending application. In response to the request contained therein, Applicant hereby indicates agreement with the stated characterization of the reference.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested.

Respectfully submitted,

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APAF - Qiagen* ARC Linkage Project (LP0455692)

"Deep-Drilling of the Human Plasma Proteome"

Dr Amit Kapur and Professor Mark Baker

Plasma is a biomarker discovery opportunity because it is easily available and because it comprehensively and regularly samples the human condition and in all states of health and/or disease. Drilling deeply into the human plasma/serum proteome with state-of-the-art technologies holds enormous promise in developing new markers for disease prognosis, diagnosis, response to therapy monitoring and stratification of patients - if some critical technical challenges are overcome.

Unfortunately, like many protein-rich biofluids (saliva, tears, urine, skin, hair, etc) plasma has an extraordinary protein concentration range. There is a 1012 difference between the concentration of the most abundant (albumin; ~60mg/mL) and rare abundance proteins. The top 20 proteins occupy the vast major of discovery space. While estimates vary, there is consensus that the 400-500 proteins reported in plasma to date are but the tip of the iceberg and that great discovery opportunities exist if we can "drill far more deeply into the human plasma proteome". Without removal of these abundant proteins visualization of the low abundance (i.e., rare) proteins is just not feasible.

The aim of this project is to investigate a novel cyclic immunodepletion technique for the removal of the high abundant proteins for human plasma using IgY antibodies. If successful this will enable the extension of the utility of current proteomic technologies to low abundant protein markers present in plasma and subsequent opportunities for research and development of new biomarkers. If successful the researchers believe the outcome could lead to a renaissance in the discovery, evaluation and deployment of novel clinical diagnostics and further enhance Australia's reputation for research excellence in Proteomics.

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